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10/013,036	10/30/2001	Jeffrey Daniel Hillman	00-1323-H	8384

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EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/013,036

Applicant(s)

HILLMAN, JEFFREY DANIEL

Examiner

Stephen Gucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 26-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-25 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/25/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-2 and 4-25, filed 9/7/04, is acknowledged. Applicant's election with traverse of species (m) *Mycobacterium* and (x) *Enterobacter*, filed 9/7/04, is also acknowledged. The traversal is on the ground(s) that no serious search burden exists for the Examiner to search all bacterial species recited in the claims. This is found persuasive and the additional Gram positive and Gram negative bacterial species recited in the instant claims are rejoined as requested by Applicant. In addition, since no prior art was found for the elected species of SEQ ID NO:7, the species of SEQ ID NO:6, 8, 9, 10, and 11 are rejoined and the search was extended to include these additional species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claim 2 is objected to for reciting an amino acid sequence without a unique SEQ ID NO. The grounds of this rejection could be obviated by amending the claim to recite SEQ ID NO:6.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 4-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,391,285 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are a sub-genus of the instant generic claims, and therefore anticipate the instant generic claims. The instant claims are the larger genus because they recite "biologically functional variants" with open language which broadens the scope of the instant claims to include many more possible species unlimited by structural limitations as compared to the patented claims which do recite structural limitations, making the patented claims the sub-genus. It is suggested by the Examiner that Applicant limit the instant claims to the species of SEQ ID NOs: 6, 7, 8, 9, or 11, thereby obviating the need for a terminal disclaimer over the parent patent.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 4-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not adequately support "biologically functional variants" because the specification only provides adequate descriptive support for lantibiotics that possess certain structural characteristics, such as having about 22 amino acids, having at least 2 lanthionine residues, at least 3 thioether bridges, at least one of both a 2,3-didehydroalanine and a 2,3-didehydrobutyrine amino acid residue, etc. However, the phrase "biologically functional variants" encompasses every compound that possesses the *functionality* of the antibiotic activity of a lantibiotic without any limitation at all regarding said compound's *structure*. The instant disclosure does not adequately describe the broad genus of compounds that may possess the antibiotic activity (e.g. penicillin, erythromycin) or other biological functions of the multiple species of lantibiotics adequately described in the specification (for instance, but not limited to, SEQ ID NO), but that do not share the chemical and structural characteristics set forth above (about 22 amino acids, etc.).
7. Claims 1 and 4-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for adequately structurally characterized lantibiotics (for instance, but not limited to, SEQ ID NO), does not reasonably provide enablement for biologically functional variants thereof. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The broad scope of these claims is not commensurate with the disclosure because while only a handful of lantibiotic species are disclosed, the claims encompass any and every compound that possess any particular biological function of a lantibiotic, such as antibiotic activity (e.g. penicillin, erythromycin), regardless of whether the structure of the compound bears any similarity to the structure of a lantibiotic. Even if the instant claims were limited to just peptides and not encompass every manner of compound, because of the high degree of unpredictability in the peptide arts regarding amino acid deletions, additions, and substitutions, and the effect these alterations have on biological activity (see Rudinger, particularly page 6), the instant disclosure is not enabling for placing this broad genus into the hands of the public.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.



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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1 and 4-25 are rejected under 35 U.S.C. 102(a) (publication date of patent) and under 35 U.S.C. 102(e) (filing date of patent) as being anticipated by Lavoie et al. (US 6,218,362 B1, "Lavoie"). The instant application is only afforded the actual filing date (10/30/01) because it is a continuation-in-part of the parent application 09/361,900, and specific support for SEQ ID NOs: 6, 7, 8, 9, 10, and 11 are not found in the parent application. Lavoie discloses instant SEQ ID NO:10 (see claim 3 and column 2, lines 60-61; column 4, lines 24-33; column 6, line 38 to column 7, line 2; column 12, line 34 to column 13, line 7; and column 14, lines 21-34). See attached sequence listing at end of Office Action. The other sequences are anticipated by Lavoie only because the generic claims encompass biologically functional variants and/or use open claim language when reciting substitutions, which leaves the claims open to encompass *additional substitutions* in addition to the substitutions explicitly recited. The grounds of this rejection for all claims *except for those reciting SEQ ID NO:10* could be obviated by amending the claims to simply recite discrete species of lantibiotics, i.e. "the isolated lantibiotic comprising SEQ ID NO:6" ; "the isolated lantibiotic comprising SEQ ID NO:7"; etc.

10. Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Smith et al. (reference 9 on PTO-1449, filed 2/25/02). Smith et al. disclose SEQ ID NO:6 (Tables 1 and 2 ; Figure 1C). The instant application is only afforded the actual filing date (10/30/01) because it is a continuation-in-part of the parent application 09/361,900, and

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specific support for SEQ ID NOs: 6, 7, 8, 9, 10, and 11 are not found in the parent application.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 11-12, 15, and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. The teachings of Smith et al. are as set forth in ¶10 above. Smith et al. does not explicitly teach detritices, bacteriocidal, or pharmaceutical compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the aforementioned compositions using the lantibiotic of Smith et al. because Smith explicitly discloses that SEQ ID NO:6 possesses antibiotic properties as well as being produced by a strain that "is a key feature in the development of replacement therapy for the prevention of dental caries" (Smith et al., page 6810),



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rendering the instant claims *prima facie* obvious because Smith et al. provides the motivation to the ordinary artisan to use SEQ ID NO:6 in detritices, bacteriocidal, and pharmaceutical compositions.

13. No claim is allowed.


14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (703) 872-9306.



Stephen Gucker

October 31, 2004



JANET ANDRES  
PRIMARY EXAMINER